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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|-------------------------|
| 10/586,718 | 04/28/2008 | Daniel Felix Awengen | 3812 | 8211 |
| 278 | 7590 | 06/16/2010 | EXAMINER | |
| MICHAEL J. STRIKER 103 EAST NECK ROAD HUNTINGTON, NY 11743 | | | | GHERBI, SUZETTE JAIME J |
| ART UNIT | | PAPER NUMBER | | |
| | | 3738 | | |
| NOTIFICATION DATE | | | DELIVERY MODE | |
| 06/16/2010 | | | ELECTRONIC | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

striker@strikerlaw.com

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/586,718 | AWENGEN ET AL. | |
| | Examiner | Art Unit | |
| | SUZETTE J-J GHERBI | 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 March 2010.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 21-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-38 is/are rejected.
- 7) Claim(s) 39 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Applicant's amendment and response dated 3/17/10 have been received in application serial number 10/86,718. All comments have been taken into consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-24, 26-29, 31, 33-34, 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurz 2002/0045939. Kurz discloses an elastic ossicular prosthesis comprising clip (41) configured to receive a stapes, And coupled to articulating ball-joint connection 42, which is coupled to a shaft lever for adjustment of frequency transmission, which comprises U-shaped clips 43 for gripping and holding an anvil (Figure 4). The socket of the ball-joint is U-shaped and has sidewalls for receiving the ball (Figure 4). The shaft lever is configured to change in angle to permit frequency adjustment, and may also be attached at different locations within the middle ear. The device is capable of connecting to an active vibration component of a hearing aid; it is

noted that there appears to be no specific structural elements of the instant prosthesis which would suggest that the Kurz prosthesis is incapable of such connection.

Alternatively, the prosthesis comprises piston 22 capable of directly connecting by way of opening a cochlea (Figure 2). The prosthesis is formed of a biocompatible synthetic material such as titanium or titanium alloy (Paragraph 9).

However Kurz does not specifically state “*means for frequency adjustment of sound transmission in a middle ear said means for frequency adjustment including lever element for changing lever conditions in the auditory ossicle chain*”. Noting [0006] Kurz does however state:

“Since the sides at the relative position of the auditory ossicles for each person is different, it is advantageous when the clip has a movable connection to a hearing device or an auditory ossicles prosthesis. Then an adjustment of the prosthesis or the hearing device of the corresponding characteristics in the middle ear is possible in situ. The movable connection can be performed for example by a shaft of a flexible material. It is however possible to provide a spherical joint between the clip and the hearing device or the prosthesis”

Kurz further states in [0023]

“It will be understood that each of the elements described above, or two or more together, may also find a useful application in other types of constructions differing from the types described above”.

It would have been obvious to one having ordinary skill in the art that the human ear contains three small bones which are also commonly referred to ossicles or collectively the ossicular chain. The three bones operate as lever systems which amplify force of sound vibrations. The stapes is in turn connected to the oval window of the inner ear. The stapes applies pressure at the oval window which is transmitted to parts of the cochlea of the inner ear (see for example 2004/0181280 Antonelli 003). It is further obvious that because the shaft 14 of Kurz is capable of being adjusted in situ that this

would alter the frequency adjustment of sound transmission (much like one changing positions along guitar strings).

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kurz (US 20020045939) in view of Kurz et al (US 6387128) "Kurz '128". Kurz does not disclose a surface roughness at a point of contact with an ossicle. However, Kurz '128 teaches an ossicular prosthesis comprising a surface roughness at the interface with an ossicular element (Column 2, Lines 6-9). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to provide a surface roughness at an ossicular interface of the Kurz prosthesis, as taught by Kurz '128, for the purpose of providing optimal abutment of the prosthesis against the ossicular element.

10. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kurz (US 20020045939) in view of Prescott (US 5554188). Kurz does not disclose forming the prosthesis of silicone. However, Prescott teaches an ossicular prosthesis formed of silicone (Column 3, Lines 17-22). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to form the Kurz prosthesis of silicone, as taught by Prescott, for the purpose of providing a material known to provide biocompatibility and elasticity for medical implants.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kurz (US 20020045939) in view of Knox et al (US 20010037151). Kurz does not disclose forming the prosthesis of a shape memory material. However, Knox teaches an ossicular

prosthesis formed of nitinol (Paragraph 38). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to form the Kurz prosthesis of nitinol, as taught by Knox, for the purpose of providing a titanium alloy having the benefits of shape memory readily appreciated of nitinol within the art.

12. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurz (US 20020045939) in view of Hurst (US 3710399). Kurz does not disclose an additional mass clipped to the prosthesis. However, Hurst teaches an ossicular prosthesis comprising magnet 3 having a mass and clipped to shafts 1 and 2 of the prosthesis (Figure 2). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to include an additional mass clipped to the Kurz prosthesis, as taught by Hurst, for the purpose of permitting frequency response according to a predetermined protocol.

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection supra.

Applicant's arguments filed 3/17/10 have been fully considered but they are not persuasive.

The intended use recitation language "means for frequency adjustment of sound transmission in a middle ear.....for changing lever conditions in the auditory ossicle chain" carries no weight in the absence of any distinguishing structure. Kurz discloses

the structure as claimed and is thus capable of performing the functions. MPEP 2114 states:

APPARATUS CLAIMS MUST BE STRUCTUR-ALLY DISTINGUISHABLE
FROM THE PRIOR ART

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus **must be distinguished from the prior art in terms of structure rather than function.** In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971);**< In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.”**

Applicant has broadened the scope of the claims by eliminating limitations i.e. claim 21 and contends that Kurz does not address “means for frequency adjust nor does Kurz disclose any “lever elements”.

The lever elements” of applicants invention are interpreted as the rods 12 and the terms seem to be utilized synonymously with respect to figures 4a-4b. The shaft of Kurz which can be adjusted as described supra are capable of sound transmission are equated to “lever elements” which are merely the rods.

Allowable Subject Matter

Claim 39 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZETTE J-J GHERBI whose telephone number is (571)272-4751. The examiner can normally be reached on Maxi-Flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SUZETTE J-J GHERBI/
Primary Examiner, Art Unit 3738
June 11, 2010